UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **MDL NO. 19-2875 (RBK)**

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF *DAUBERT* MOTION TO PRECLUDE DEFENSE EXPERT DAVID L. CHESNEY FROM OFFERING CLASS CERTIFICATION OPINIONS

MAZIE SLATER KATZ & FREEMAN, LLC
103 Eisenhower Parkway, Suite 207
Roseland, New Jersey 07068
973-228-9898
973-228-0303 fax

On the Brief:
Adam M. Slater, Esq.
Christopher Geddis, Esq.

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PRELIMINARY STATEMENT

David Chesney unequivocally disavowed any expertise or opinions regarding class certification in his deposition. Defendants cite David Chesney's report a mere three times in their opposition to class certification. Those references were all made in the factual background of the brief, and they do not bear on the merits of class certification, which is the sole set of issues for which this round of experts was offered. Therefore, Mr. Chesney's opinions do not fit this part of the case and should be precluded. More substantively, the three specific opinions are unsupported and the result of a conclusion-driven approach in violation of *Daubert*, requiring their preclusion.

Plaintiffs also note that Defendants do not oppose their motion to preclude Mr. Chesney from opining on parties other than ZHP, the TEA manufacturing process, and finished dose products. At a minimum, the Court should preclude these opinions.

LEGAL ARGUMENT

I.

DAVID CHESNEY DID NOT OPINE AGAINST RULE 23 PREDOMINANCE

Defendants argue that Mr. Chesney's opinions fit their opposition to class certification because they "bear directly on issues at the heart of the Rule 23 predominance inquiry." (ECF 2080, p. 4). However, Defendants did not cite or discuss his opinions in their brief discussing predominance.[1] (ECF 2008, p. 20-63). Moreover, Mr. Chesney was clear that class certification, including predominance, "is not within my area of expertise, and I did not address it." (Chesney Dep. Tr. 40:5-18, Ex. 1 to ECF 2038-3). To the extent Mr. Chesney did opine on predominance, he agreed that ZHP's defective risk assessment for the zinc chloride manufacturing process

[1] In the next section, Plaintiffs discuss the three propositions for which Defendants actually cite Mr. Chesney's opinions. Plaintiffs also note that Defendants rely on inapposite cases in support of Mr. Chesney's fit for the class certification of this case.

rendered all of ZHP's valsartan manufactured with that process in violation of cGMP and therefore adulterated. (*Id.* at 114:12-115:3).

The Court should consequently preclude Mr. Chesney from providing class certification opinions. *See Lewis v. Gov. Employees Ins. Co.*, Civil No. 18-5111 (RBK/MJS), 2022 WL 819611, at *5 (D.N.J. Mar. 18, 2022) **(Kugler, J.)** (precluding a proposed class expert witness after testifying "at his deposition that he is not giving any opinions on whether class certification is appropriate") (Ex. 1);[2] *see also Dominguez v. Yahoo, Inc.*, 894 F.3d 116, 121 (3d Cir. 2018) (holding that the expert declaration, "like the other expert reports, lacks fit or relevance and was therefore properly excluded.").

II.

DAVID CHESNEY'S THREE OPINIONS ARE NOT WELL SUPPORTED

"As a gatekeeper, courts are supposed to ensure that the testimony given to the jury is reliable and will be more informative than confusing." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017). Additionally, "[b]oth an expert's methodology and the application of that methodology must be reviewed for reliability." *Id.* at 791. The "specific way an expert conducts such an analysis must be reliable; '**all of the relevant evidence must be gathered**, and **the assessment or weighing of that evidence must not be arbitrary**, but must itself be **based on methods of [the relevant field].**'" *Id.* at 796 (emphasis added).

More specifically, an "expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow*

[2] Unless otherwise noted, all exhibits are included in the certification of Adam M. Slater in support of this reply brief.

Pharmaceuticals, Inc., 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis, and "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* at 745. In addition, the following factors are relevant when determining reliability:

> (i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997)); (iii) **whether the expert has adequately accounted for alternative explanations** (*see Claar v. Burlington, N.R.R.,* 29 F.3d 499 (9th Cir. 1994)).

Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584, 594–95 (D.N.J. 2002) (emphasis added), *aff'd,* 68 Fed. Appx. 356 (3d Cir. 2003). To this end, the Third Circuit has affirmed the exclusion of expert testimony that "failed to consistently apply the … methods … articulate[d], … deviated from or downplayed certain well-established principles of [the] field, and … **inconsistently applied methods and standards to the data so as to support [an] a priori opinion**." *Zoloft*, 858 F.3d at 792 (emphasis added).

Here, Defendants cited Mr. Chesney's report three times in their class certification briefing. First: "Plaintiffs make various false allegations about ZHP, including that it: (1) changed its manufacturing process to 'save money' and 'dominate the world market share'; and (2) failed to conduct an 'adequate' risk assessment, leading to an 'out of control' manufacturing process. See EL Br. at 9-11. These attacks are both irrelevant and directly contrary to the record." (ECF 2008, p. 10 (citing Ex. 194, Chesney Rep. at 53-59 (also attached as Ex. 5 to Pls.' Initial Br. under seal))). In opposition to Plaintiffs' motion to preclude the above opinion, Defendants do not maintain that Mr. Chesney supports (1). As a result the Court should bar him from providing such an opinion.

Focusing on (2), ZHP contends that "Mr. Chesney's disagreement with the findings of the FDA in its November 2018 Warning Letter is consistent with his report." (ECF 2080, p. 12 (citing Chesney Rep. at 39, 53-59)). However, ZHP omits the preceding sentence from page 39 of his report, where he states that **"the disputes over factual accuracy center on scientific/technical issues and interpretations that involve expertise I normally rely upon others to provide."** (Chesney Rep., p. 39 (emphasis added)). During his deposition, Mr. Chesney repeated this disclaimer whenever he was presented with evidence disfavoring his opinions. (*See, i.e.*, Chesney Tr., 69:20-70:9, 119:12-14, 126:18-20, 138:4-7, 191:2-19). He admitted that he did not discuss or rely on "any particular subject matter experts regarding the science to form [his] opinions." (*Id.* at 79:21-80:2). *Daubert* does not allow an expert to proffer this type of a priori opinion. *Zoloft*, 858 F.3d at 792. The Court must exclude it.

In their opposition to class certification, Defendants also wrote, "FDA did not declare any VCDs or API used to manufacture VCDs 'adulterated' until, at the earliest, November 29, 2018…." (ECF 2008, p. 18 (citing Ex. 194, Chesney Rep., 4-5, 18)). Plaintiffs previously argued that "ZHP cannot rely on Mr. Chesney for the opinion that ZHP's valsartan only became adulterated on November 29, 2018," as the warning letter was clear that **"[i]n November 2011[,] …. you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process,**" and this constituted a cGMP violation. (ECF 2038-1, p. 30 (citing *See Zoloft*, 858 F.3d at 800); *see also* FDA's November 29, 2018 Warning Letter (Ex. 2)). As with the previous proposition, Mr. Chesney may "disagree" with the FDA, but he does not have a sound methodology or basis for that disagreement, and his purpose-driven, a priori opinions are impermissible under *Daubert*. *Zoloft*, 858 F.3d at 792. To the extent no expert may testify that a drug product was adulterated, as ZHP seems to argue on page 16 of its brief, the opposite must

also be true—no expert can testify that it was not adulterated. (ECF 2080, p. 16 (stating an "expert 'cannot take the final step of opining that the product was 'misbranded' or 'adulterated,' as these are impermissible legal conclusions"). Presumably, if that is the case, then the experts can opine as to the predicates for adulteration with the Court or jury to determine whether the criteria are met. Nonetheless, this rule would also prohibit Mr. Chesney from offering this second opinion. The Court should therefore preclude him from offering it.

Third, Defendants cited Mr. Chesney for the proposition that "[a]t all relevant times prior to each manufacturer's recall, all VCDs met their compendial and approved Drug Master File and ANDA specifications and their labeling conformed to the RLDs." (ECF 2008, p. 18 (citing Ex. 194, Chesney Rep. at 4-5, 49-50)). ZHP argues that Mr. Chesney did not need to review the compendial USP standard to support this opinion, as "[t]his contention erroneously assumes that an expert must review every scrap of potentially relevant data before forming an opinion." (ECF 2080, p. 17). Although ZHP cites cases in support of this uncontroversial rule, they are inapposite. The USP is not an extraneous "scrap of potentially relevant data." It is the standard that Mr. Chesney claims ZHP met when manufacturing its valsartan. *Daubert* does not allow an expert to testify a standard was met without having reviewed that standard. *See Zoloft*, 858 F.3d at 796. The Court must preclude this opinion.

ZHP ends its argument on all three opinions citing *Benham v. Ozark Materials River Rock, LLC*, No. 11-CV-339-JED-FHM, 2013 WL 5592975, at *3 (N.D. Okla. Oct. 10, 2013), explaining that an expert's opinions may be "based on the 'inspection reports of the agencies and those agencies' lack of finding of any violations of the Clean Water Act." (ECF 2080, p. 18). This is a strange way to end an argument in support of Mr. Chesney's opinions, which ZHP concedes directly contradict the FDA's 2018 Warning Letter and EIR, both documenting numerous serious

cGMP violations related to the manufacture of ZHP's nitrosamine-contaminated valsartan. (Ex. 2; Ex. 4 to ECF 2038-6). Rather than support the admission of Mr. Chesney's opinions, this argument highlights his impermissibly results-driven approach, where the FDA is trusted if it supports his client's position but is disregarded without analysis or support if it does not. *See Zoloft*, 858 F.3d at 792. The Court's gatekeeping role would require the exclusion of these opinions on this basis as well.

III.

DEFENDANTS DO NOT OPPOSE PLAINTIFFS' MOTION TO PRECLUDE DAVID CHESNEY FROM OPINING ON PARTIES OTHER THAN ZHP, THE TEA MANUFACTURING PROCESS, AND FINISHED DOSE PRODUCTS

Plaintiffs asked the Court to preclude David Chesney from opining as to a party other than ZHP, the TEA manufacturing process, and finished dose products. (ECF 2038-1, p. 19, 21). Defendants do not oppose this part of Plaintiffs' motion.[3] The Court should therefore grant this relief.

[3] Defendants instead misinterpret Plaintiffs' request as an argument related to the admissibility of Mr. Chesney's other opinions, which as they agree, makes no sense. (ECF 2080, p. 9-10).

CONCLUSION

For the foregoing reasons, Mr. Chesney should be precluded from offering any opinions related to whether the claims are appropriate for class treatment, opinions regarding subjects he did not evaluate or opine on, and nor should ZHP be permitted to rely on Mr. Chesney's opinions in an effort to oppose class certification to the extent that reliance is based on net opinions lacking adequate foundation and analysis.

Respectfully,

PLAINTIFFS' CO-LEAD COUNSEL

By: /s/Adam M. Slater

ADAM M. SLATER
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068
973-228-9898
Fax: 973-228-0303
aslater@mazieslater.com

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